

# **OPCON-A- naphazoline hydrochloride and pheniramine maleate solution/ drops**

**Bausch & Lomb Incorporated**

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## **Drug Facts**

### **Active ingredients**

Naphazoline HCl (0.02675%)

Pheniramine maleate (0.315%)

### **Purposes**

Redness reliever

Antihistamine

### **Uses**

- temporarily relieves itching and redness caused by pollen, ragweed, grass, animal hair and dander

### **Warnings**

**For external use only**

### **Do not use**

- if you are sensitive to any ingredient in this product
- if solution changes color or becomes cloudy

### **Ask a doctor before use if you have**

- heart disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- narrow angle glaucoma

### **When using this product**

- overuse may cause more eye redness
- pupils may become enlarged temporarily
- do not touch tip of container to any surface to avoid contamination
- you may feel a brief tingling after putting drops in eye
- replace cap after use
- remove contact lenses before using

## **Stop use and ask a doctor if you experience**

- eye pain
- changes in vision
- redness or irritation of the eye that worsens or lasts more than 72 hours

## **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away. Accidental oral ingestion in infants and children may lead to coma and marked reduction in body temperature.

## **Directions**

- **Adults and children 6 years of age and older:** Instill 1 or 2 drops in the affected eye(s) up to 4 times daily.
- **Children under 6 years:** ask a doctor

## **Other information**

- store at 20-25 °C (68-77 °F)
- this package is child-resistant
- protect from light
- use before expiration date marked on the carton or bottle

## **Inactive ingredients**

benzalkonium chloride, boric acid, edetate disodium, hypromellose, purified water, sodium borate, sodium chloride. Hydrochloric acid may be used to adjust pH.

## **Questions or comments?**

[phone icon] **call: 1-800-553-5340**

## **Distributed by:**

Bausch & Lomb Americas Inc.  
Bridgewater, NJ 08807 USA

## **Package/Label Principal Display Panel**

3328

**TWIN PACK****NDC 24208-430-45****BAUSCH + LOMB**

**Opcon-A<sup>®</sup>**  
**pheniramine maleate 0.315% and naphazoline**  
**hydrochloride 0.02675% ophthalmic solution**  
**ANTI-HISTAMINE AND REDNESS RELIEVER**

**EYE DROPS**  
**CLINICALLY PROVEN**  
**EYE ALLERGY RELIEF**

itching + redness

caused by pollen, ragweed, grass, animal hair and dander

[teardrop icon]

STERILE

**2 x 15 mL BOTTLES**

(0.5 FL OZ EACH)

**3844801**

**AB55299**

## OPCON-A

naphazoline hydrochloride and pheniramine maleate solution/ drops

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:24208-430 |
| <b>Route of Administration</b> | OPHTHALMIC     |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength         | Strength          |
|---|---------------------------|-------------------|
| <b>NAPHAZOLINE HYDROCHLORIDE</b> (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV) | NAPHAZOLINE HYDROCHLORIDE | 0.2675 mg in 1 mL |
| <b>PHENIRAMINE MALEATE</b> (UNII: NYW905655B) (PHENIRAMINE - UNII:134FM9ZZ6M)       | PHENIRAMINE MALEATE       | 3.15 mg in 1 mL   |

### Inactive Ingredients

| Ingredient Name                                     | Strength |
|---|----------|
| <b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)     |          |
| <b>BORIC ACID</b> (UNII: R57ZHV85D4)                |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)          |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                     |          |
| <b>SODIUM BORATE</b> (UNII: 91MBZ8H3QO)             |          |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)           |          |
| <b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)         |          |
| <b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO) |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:24208-430-03 | 1 in 1 CARTON   | 08/06/1994           | 04/01/2013         |
| 1 |                  | 3 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product  |                      |                    |
| 2 | NDC:24208-430-15 | 1 in 1 CARTON   | 08/06/1994           |                    |
| 2 |                  | 15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product |                      |                    |
| 3 | NDC:24208-430-30 | 1 in 1 CARTON   | 08/06/1994           | 07/01/2011         |

|   |                  |   |            |  |
|---|------------------|---|------------|--|
| 3 |                  | 30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product |            |  |
| 4 | NDC:24208-430-45 | 2 in 1 CARTON   | 07/01/2015 |  |
| 4 |                  | 15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product |            |  |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA                | NDA020065                                | 06/08/1994           |                    |

**Labeler** - Bausch & Lomb Incorporated (196603781)

## Establishment

| Name                       | Address | ID/FEI    | Business Operations    |
|----------------------------|---------|-----------|------------------------|
| Bausch & Lomb Incorporated |         | 079587625 | MANUFACTURE(24208-430) |

Revised: 12/2023

Bausch & Lomb Incorporated